



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,403	12/12/2001	Robert J. Schwartz	108328.00031 (AVSI-0009)	3652
52316	7590	12/16/2008	EXAMINER	
Pepper Hamilton LLP 400 Berwyn Park 899 Cassatt Road Berwyn, PA 19312-1183			HAMA, JOANNE	
			ART UNIT	PAPER NUMBER
			1632	
			MAIL DATE	DELIVERY MODE
			12/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/021,403	Applicant(s) SCHWARTZ ET AL.	
	Examiner JOANNE HAMA	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 140-154 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 140-154 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant filed a response to the Non-Final Action of April 1, 2008 on September 2, 2008. Claims 1-139 are cancelled. Claim 154 is new. Claim 140 is amended.

Claims 140-154, drawn to a method of improving weight gain and development in a mammalian litter that does not comprise exogenous nucleic acid sequences, wherein an expression construct comprising the coding region of GHRH is administered to the mother, is under consideration.

Withdrawn Rejections

35 USC § 112, 1st parag., New Matter.

Applicant's arguments, see page 9 of Applicant's response, filed September 2, 2008, with respect to the rejection of claims 140-153 have been fully considered and are persuasive. Applicant indicates that claim 140 has been amended. Claims 141-153 depend on claim 140 and were included in the rejection. The rejection of claims 140-153 has been withdrawn.

35 USC § 112, 2nd parag.

Applicant's arguments, see page 9 of Applicant's response, filed September 2, 2008, with respect to the rejection of claims 140-153 have been fully considered and are persuasive. Applicant indicates that claim 140 is amended. Claims 141-153 depend on claim 140 and were included in the rejection. The rejection of claims 140-153 has been withdrawn.

New/Maintained Rejections

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 140, 143-153 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21-23 of Schwartz et al., U.S. Patent No. 6,423,693 ('693) previously cited, in view of Aihara et al., 1998, Nature Biotechnology, 16: 867-870, previously cited, Kann et al. U.S. Patent 5,061,690 ('690), previously cited, Tsukamoto et al., 1995, Nature Genetics, 9: 243-248, Schwartz et al., US Patent 6,551,996 ('996), Li et al., 1999, Nature Biotechnology, 17, 1999, see IDS filed May 25, 2005, Gilbert et al., 1997, Biochimica et Biophysica Acta, 1334: 9-14, Hui et al., US Patent 5,789,213, patented August 4, 1998, Nabel et al., US Patent 5,910,488, patented June 8, 1999, for reasons of record, April 1, 2008.

Applicant's arguments filed September 2, 2008 have been fully considered but they are not persuasive.

Applicant indicates that it is well established that the double patenting rejection of the obviousness-type, if not based on an anticipation rationale is analogous to a failure to meet the nonobviousness requirement of 35 USC § 103 except that the patent principally underlying the patent rejection is not considered prior art. The analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 USC § 103 obviousness determination. The concepts of obviousness and inherency are distinct and an obviousness rejection based on inherency analysis is improper. Applicant indicates that the Office has improperly based its obviousness analysis on inherency (Applicant's response, page 6). In response, this is not persuasive. As indicated in the Office Action, April 1, 2008, page 8, regardless of whether '693 or Aihara et al. were aware or not that introducing pSK-GHRH to pregnant mice would result in mouse pups that exhibit improved weight gain and development, the mouse pups would have exhibited this characteristic because it is inherent to the method. That is, combining '693 and Aihara et al. would result in the same method as that claimed and because the method steps are the same, the end result of increased weight and development in a litter would have been achieved, regardless if either '693 or Aihara et al. were aware of that result. Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his

Art Unit: 1632

claimed product. See *In re Ludtke* 441 F.2d 660, 169 USPQ 563 (CCPA 1971). Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

Thus, the claims remain rejected.

Claims 140, 141, 143-147 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 8-11, 15, 16 U.S. Patent 7,250,405 ('405) (Draghia-Akli et al.), previously cited, and Tsukamoto et al., 1995, *Nature Genetics*, 9: 243-248, Louisiana Veterinary Medical Association, *Biology of the Rat* [online], 2007 [retrieved on 2007-03-28]. Retrieved from the Internet:< URL: <http://www.lvma.org/rat.html>>, pages 1-8, for reasons of record, April 1, 2008.

Applicant's arguments filed September 2, 2008 have been fully considered but they are not persuasive.

Applicant indicates that the rejection of claims 140, 141, 143-147 is improper because the analysis employed by the Office to arrive at the conclusion that the claims of the instant application are obvious in light of claims 1-4, 8-11, 15, 16 of '405 is improperly based upon inherency. Assuming, arguendo, the Office analysis were analyzed solely based upon as an obviousness analysis, the rejection is still improper

Art Unit: 1632

because the combined teachings '405 and Tsukamoto do not recite every element of the claims. Further, Tsukamoto teaches away from the claimed invention. Thus, one of ordinary skill in the art would not find claims 140, 141, 143-147 to be obvious over '405 in view of Tsukamoto (Applicant's response, page 7-8). In response, the obviousness-type double patenting was raised because the scope of the patented claims in '405 overlaps with that of the instant application. Tsukamoto et al. was not relied upon to be combined in a 103 type analysis, but was provided to teach that because the methods of administering expression vector via saline or PBS was same between '405 and the instant application, the litter of rat pups taught in '405 would not have taken up any expression vector (Office Action, April 1, 2008, page 10). Again, because the method steps between '405 and the instant application were the same, the rat pups taught in '405 would have not taken up any expression vector and would have exhibited improved weight gain and development. Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See *In re Ludtke* 441 F.2d 660, 169 USPQ 563 (CCPA 1971). Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. In *re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

With regard to Tsukamoto et al., Applicant indicates that the Office analysis is improper because the Office conclusion is based upon a negative inference in view of the disclosures of Tsukamoto. Tsukamoto does not teach or suggest intramuscular injection of DNA. The combination of the cited claims of '405 and Tsukamoto fail to teach or suggest transmission of nucleic acid construct to litters of treated mothers through intramuscular mother (Applicant's response, page 8). In response, this is not persuasive. The Examiner relied on '405 for teaching intramuscular injection of mothers ('405, abstract). Again, Tsukamoto et al. was provided to illustrate that expression vectors administered via PBS or saline do not reach the fetuses. As such, Tsukamoto et al. was provided to illustrate that the method taught in '405 does practice administration of nucleic acid to a mother without the nucleic acid entering the fetus.

Applicant indicates that in combining '405 and Tsukamoto et al., the Office has picked out those passages which support their position with respect to a prima facie case and disregarded the teachings which teach away and do not support a prima facie case of obviousness (Applicant's response, pages 8-9). In response, this is not persuasive. All the teachings were provided in '405. Tsukamoto et al. was provided to illustrate that the fetuses did not take up any nucleic acid construct. With regard to the issue of picking out passages, the Examiner has considered the teachings as a whole and honed in on specific regions in the cited texts to address the specific limitations recited in the claims.

Thus, the claims remain rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 140, 143-153 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al., U.S. Patent No. 6,423,693 ('693), previously cited, in view of Aihara et al., 1998, Nature Biotechnology, 16: 867-870, previously cited, Kann et al. U.S. Patent 5,061,690 ('690) previously cited, Tsukamoto et al., 1995, Nature Genetics, 9: 243-248, Schwartz et al., US Patent 6,551,996 ('996), Li et al., 1999, Nature Biotechnology, 17, 1999, see IDS filed May 25, 2005, Gilbert et al., 1997, Biochimica et Biophysica Acta, 1334: 9-14, Hui et al., US Patent 5,789,213, patented August 4, 1998, Nabel et al., US Patent 5,910,488, patented June 8, 1999, for reasons of record, April 1, 2008.

Applicant's arguments filed September 2, 2008 have been fully considered but they are not persuasive.

Applicant indicates that in combining the references, the Office has picked out those passages which support their position with respect to a prima facie case of obviousness and disregarded those teachings which teach away. This is improper and expressly contrary to a well established legal precedent. When all of the teachings of the references are taken into account, it is overwhelmingly clear that the combination of references is improper and therefor does not produce a prima facie case of

Art Unit: 1632

obviousness. The Tsukamoto reference specifically teaches away from the claimed invention (Applicant's response, page 11). In response, this is not persuasive.

Applicant asserts that the Tsukamoto reference specifically teaches away, but provides no argument indicating what about the reference teaches away from combining the references to arrive at the claimed invention. If Applicant is referring to the above argument with regard to Tsukamoto et al., wherein Tsukamoto et al. do not teach intramuscular delivery, Aihara et al. teach intramuscular delivery of a nucleic acid expression vector (Office Action, April 1, 2008, page 4). As indicated in the Office Action, because the method of electroporation and muscular delivery of an expression construct was known, an artisan would have taken the teaching of '693 and adapted the teaching of Aihara et al. to it. With regard to Applicant indicating that the Examiner has picked out those passages which support their position with respect to a prima facie case of obviousness and disregarded those teachings which teach away, the Examiner has considered the teachings as a whole and honed in on specific regions in the cited texts to address the specific limitations recited in the claims.

Thus, the claims remain rejected.

Claims 140-153 remain rejected and new claim 154 is newly rejected under 35 U.S.C. 103(a) as being unpatentable over Kann et al. U.S. Patent 5,061,690 ('690), previously cited, in view of Draghia-Akli et al., 1997, Nature Biotechnology, 1285-1289, see IDS, filed May 25, 2005, Aihara et al., 1998, Nature Biotechnology, 16: 867-870, previously cited, Infoplease, Gestation, Incubation, and Longevity of Selected Animals

Art Unit: 1632

[online], 2005 [retrieved on 2007-03-28]. Retrieved from the Internet:< URL: <http://www.infoplease.com/ipa/A0004723.html>>, pages 1-3, Tsukamoto et al., 1995, Nature Genetics, 9: 243-248, Schwartz et al., US Patent 6,551,996 ('996), Li et al., 1999, Nature Biotechnology, 17, 1999, see IDS filed May 25, 2005, Gilbert et al., 1997, Biochimica et Biophysica Acta, 1334: 9-14, Hui et al., US Patent 5,789,213, patented August 4, 1998, Nabel et al., US Patent 5,910,488, patented June 8, 1999, for reasons of record, April 1, 2008.

Applicant's arguments filed September 2, 2008 have been fully considered but they are not persuasive.

Applicant indicates that Kann does not teach intramuscular injection and an ordinary artisan would not find the results of one mode of administration obvious in view of the results of an experiment performed with another mode of administration. Further, there is no recognizable benefit in modifying Kann to include intramuscular injection (Applicant's response, page 12). In response, this is not persuasive. As indicated in the Office Action, April 1, 2008, pages 15-16, Kann teaches administration of GHRH protein to pregnant ewes. Draghia-Akli et al. teach an expression construct of pSK-GHRH that was injected into the muscle of mice. Aihara et al. teach that in vivo electroporation of a transgene construct provides an efficient approach for muscle-targeted gene expression. As such, it would have obvious for an artisan to substitute GHRH protein with that of an expression vector and inject the expression into the muscle and use electroporation. An artisan would have done so because Draghia-Akli et al. teach that GHRH protein can be expressed from an expression construct and

Art Unit: 1632

because Aihara et al. teach that electroporation and injection into the muscle provides an efficient approach for muscle targeted gene expression.

Applicant indicates that the combination of Drahi-Akli, Aihara, Kann, and Tsukamoto do not render the invention recited in claim 140 obvious because the combination of the references fail to teach the elements of the claims. As discussed above, Tsukamoto et al. teach away from the claimed invention (Applicant's response, page 12). In response, as discussed above, Tsukamoto et al. does not treat away. Tsukamoto et al. was used to illustrate that pregnant mothers administered expression construct suspended in saline or PBS do not have litters that take up expression construct.

Thus, the claims remain rejected.

Conclusion

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

Art Unit: 1632

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Mondays, Tuesdays, Thursdays, and Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has

Art Unit: 1632

been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Joanne Hama/
Primary Examiner
Art Unit 1632